UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/870,762	06/06/1997	BRADFORD J. DUFT	226/104US	7328

44638 7590 03/01/2010

Intellectual Property Department
Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, CA 92121

EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	
MAIL DATE	**DELIVERY MODE**
03/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/870,762	DUFT ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *102009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-17* is/are pending in the application.

4a) Of the above claim(s) _ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *022510*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed 10/20/09 has been entered.

Applicants' Withdrawal of their Appeal

2) With the filing of the RCE, Applicants withdraw their appeal to the Board of Patent Appeals and Interferences.

Appeal Dismissed by the Board

3) It is noted that the Board of Patent Appeals and Interferences has issued an order on 12/14/09 dismissing Applicants' appeal.

Applicants' Response

4) Acknowledgment is made of Applicants' amendment filed 10/20/09 in response to the Advisory action mailed 04/30/2008 and the final Office Action mailed 02/11/08.

Information Disclosure Statement

5) Acknowledgment is made of Applicants' Information Disclosure Statement filed 02/25/10. The information referred to therein has been considered, and a signed copy is attached to this Office Action.

Status of Claims

6) No claims have been amended.

Claims 1-7 and 9-17 are pending and are under examination.

Prior Citation of Title 35 Sections

7) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

8) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Maintained

9) The rejection of claims 7, 14, 16 and 17 made in paragraph 26 of the Office Action mailed 02/11/08 and maintained in paragraph 11 of the Office Action mailed 04/30/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34 and 35 of the US patent 5,686,411 issued to Gaeta *et al.* ('411, of record) as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record), is maintained for the reasons set forth therein and in the Examiner's answer mailed 10/20/09.

10) The rejection of claims 7, 14 and 16 made in paragraph 27 of the Office Action mailed 02/11/08 and maintained in paragraph 12 of the Office Action mailed 04/30/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11 and 13 of US patent 5,321,008 issued to Beumont *et al.* as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record) and Rink *et al.* (US 5,739,106, of record) ('106), is maintained for the reasons set forth therein and in the Examiner's answer mailed 10/20/09.

11) The rejection of claims 1, 7, 14 and 16 and the dependent claims 2-6, 9-13, 15 and 17 made in paragraph 28 of the Office Action mailed 02/11/08 and maintained in paragraph 13 of the Office Action mailed 04/30/08 under 35 U.S.C § 112, first paragraph, as containing new matter, is maintained for the reasons set forth therein and in the Examiner's answer mailed 10/20/09.

12) The rejection of claims 1-7 and 9-17 made in paragraph 29 of the Office Action mailed 2/11/08 and maintained in paragraph 14 of the Office Action mailed 04/30/08 under 35 U.S.C § 112, first paragraph, as being non-enabling with regard to the scope, is maintained for the reasons set forth therein and in the Examiner's answer mailed 10/20/09.

13) The rejection of claims 1-7, 9-14, 16 and 17 made in paragraph 33 of the Office Action mailed 02/11/08 and maintained in paragraph 15 of the Office Action mailed 04/30/08 under 35 U.S.C § 102(a) as being anticipated by Kolterman *et al.* (WO 96/40220, of record) as evidenced by

Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record), is maintained for the reasons set forth therein and in the Examiner's answer mailed 10/20/09.

14) The rejection of claims 7, 14 and 16 made in paragraph 34 of the Office Action mailed 02/11/08 and maintained in paragraph 16 of the Office Action mailed 04/30/08 under 35 U.S.C § 102(e)(2) as being anticipated by Beumont *et al.* (US 5,321,008, of record) ('008) as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record), is maintained for the reasons set forth therein and in the Examiner's answer mailed 10/20/09.

15) The rejection of claims 7, 14, 16 and 17 made in paragraph 35 of the Office Action mailed 02/11/08 and maintained in paragraph 17 of the Office Action mailed 04/30/08 under 35 U.S.C § 102(e)(2) as being anticipated by Gaeta *et al.* (US 5,686,411, of record) ('411) as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record), is maintained for the reasons set forth therein and in the Examiner's answer mailed 10/20/09.

16) The rejection of claims 1-7, 9, 11-14, 16 and 17 made in paragraph 36 of the Office Action mailed 02/11/08 and maintained in paragraph 18 of the Office Action mailed 04/30/08 under 35 U.S.C § 102(b) as being anticipated by Kolterman *et al.* (*Diabetologia* 39: 492-499, April, 1996, of record) (Kolterman *et al.*, 1996) as evidenced by Itasaka *et al.* (*Psychiatr. Clin. Neurosci.* 54: 340-341, June 2000, of record), is maintained for the reasons set forth therein and in the Examiner's answer mailed 10/20/09.

Response to Applicants' Arguments

17) Applicants submit Exhibit 1 and the following arguments. The specific rejections to which the evidence and the arguments are applicable are stated as those that are set forth at sections 26 and 27 of the Final Office Action asserting double patenting, and sections 33, 34, 35 and 36 asserting anticipation. Applicants' Exhibit I apparently demonstrates that weight loss was not observed in all patients who had diabetes and in many cases were also obese, that were administered pramlintide specifically to treat their diabetes by controlling their blood sugar. Applicants state that as indicated in page 1 of Exhibit I, pramlintide was administered at 120 micrograms twice a day to patients with diabetes and *who were also taking insulin* (Group A). The results at pages 3-4 of Exhibit I are stated as showing the proportion of patients that did not gain weight (either lost weight or were weight neutral) with pramlintide treatment (i.e., Group A)

to be 46.4%, indicating that 53.6% did gain weight. Applicants submit that a patient treated for control of blood sugar according to the cited art would not have necessarily and inevitably also achieved weight loss. Applicants state that the evidence provides concrete support for their previous arguments and cited case law demonstrating a lack of inherency in the cited art. Applicants assert that to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. *In re Robertson,* 169 F.3d 743, 745 (Fed. Cir. 1999). Applicants further state that the fact that a certain result or characteristic may be present in the prior art is not sufficient to establish the inherency--inherency may not be established by probabilities or possibilities. *Continental Can Co. USA, Inc., v. Monsanto Co., 948 F.2d 1264, 1268* (Fed Cir. 1991); *In re Rijckaert,* 9 F.3d 1531, 1534 (Fed. Cir. 1993). Applicants argue that it is not sufficient that a person following the teachings of the cited art sometimes obtains the claimed result -- it must invariably happen. Applicant submits that the cited art does not inherently anticipate the claimed methods for the reasons already of record and further in view of the evidence submitted herewith.

Applicants' arguments and the evidence have been carefully considered, but are not persuasive. As has been established in detail at paragraphs 10(III), 10(IV), 10(V), 10(VI), 10(VII) and 10(VIII) of the Examiner's answer mailed 10/20/09; at paragraphs 11, 12, 15, 16, 17 and 18 of the Office Action mailed 04/30/08; and at paragraphs 26, 27, 33, 34, 35 and 36 of the Office Action mailed 02/11/08, the prior art method necessarily includes all of the elements of the instant claims.

The extrinsic evidence does make clear that the missing descriptive matter is necessarily present in the thing described in the applied references and therefore establishes inherency. As set forth previously, that the determination of inherency in the instant case is not established by probabilities or possibilities is evidenced by the teachings of Thompson *et al.* (*Diabetes* 46: Suppl. 1, page 30A, 0116, 02 May 1997, of record) (Thompson *et al.* May, 1997). The reference of Thompson *et al.* establishes that the missing inherent matter is necessarily present in the method thing described in the prior art reference. Thompson *et al.* (May, 1997) showed that a method of subcutaneous administration of pramlintide, i.e., $^{25, 28, 29}$pro-h-amylin, an analog of human amylin, i.e., the same amylin agonist used in the instant invention, to patients with type II diabetes requiring insulin, at a dose 60 micrograms QID (i.e., four times a day) or TID (i.e., three times a

day) not only improved glycemic control in these patients, ***but also decreased body weight*** concurrently (see abstract) and therefore necessarily served as a method of treating obesity. it is important to note that the *human patients used in the instant specification for treatment of obesity via administration of pramlintide are indeed type II diabetic human patients*. As set forth previously, the prior art disclosure is commensurate in scope with the instant disclosure with regard to the type 2 diabetic human subject population used, the pramlintide compound administered, the amount and frequency of pramlintide administered, to the type 2 diabetic human patients. The same two methods (i.e., the prior art method and the instant method) cannot have mutually exclusive results.

Similarly, that the determination of inherency in the instant case with regard to the method of Kolterman (1996) is certainly not established by probabilities or possibilities is further evidenced by the teachings of Rattner *et al.* (*Exp. Clin. Endocrinol. Diabetes* 113: 199-204, 2005, of record) (Rattner *et al.* 2005). The reference of Rattner *et al.* (2005) is set forth herein solely to address Appellants' arguments. The reference of Rattner *et al.* (2005), which is co-authored by the inventor OG Kolterman, show that subcutaneous administration of 30 or 60 micrograms of TID or QID pramlintide to insulin-taking IDDM patients having a body weight of 76.0 ± 14.3 kg or a BMI of > 25 kg/m^2, concurrently induced *a significant decline in weight*. See sections 'Subjects and Methods'; Results; Table 1; and Figure 1B of Rattner *et al.* (2005). Therefore, Kolterman's (1996) method necessarily served as a method of treating obesity. It is particularly noted that Appellants have advanced no arguments with regard to the teachings of Rattner *et al.* (2005), the reference that was cited to show that the missing inherent matter is necessarily present in the method thing described in the prior art reference of Kolterman *et al.* (1996).

As set forth previously, an anticipatory reference has to teach only one species or one embodiment encompassed by the scope of the genus claims. Under the principles of inherency, a reference may be directed to an entirely different problem than the one addressed by the inventor, or may be from an entirely different field of endeavor than that of the claimed invention, yet the reference is still anticipatory if it explicitly or inherently discloses every limitation recited in the claims. See *State Contracting & Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1068, 68 USPQ2d 1481, 1488 (Fed. Cir. 2003). Applicants appear to be arguing that in order to be

anticipatory, a prior art reference has to teach each and every species or embodiment encompassed within the scope of the instant claims. The argument is not persuasive.

The evidence of record in the instant case establishes that obesity was known to be associated and/or interrelated with type 2 diabetes mellitus in humans. See Tsanev's teachings. The applied prior art references taught the administration of pramlintide to human type II diabetes mellitus patients as explained *supra*. The extrinsic evidence from Thompson establishes that the prior art method necessarily results in weight loss in this patient population. Appellants have not identified any manipulative difference between Kikuchi-Hayakawa's method and the claimed method. As discussed above, the claimed method is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art" (*Perricone,* 432 F.3d at 1377), regardless of whether the inherent result is recognized. "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff,* 919 F.2d *1575,* 1578 (Fed. Cir. 1990). When "a claimed new benefit or characteristic of an invention otherwise in the prior art" is an inherent property of the old invention, "the new realization alone does not render the old invention patentable." *Perricone v. Medicis Pharm. Corp.,* 432 F.3d 1368, 1377 (Fed. Cir. 2005). "[A] limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior *art." Id.* (citations omitted). As summarized in *Perricone, id.* at 1375-76: A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.,* 976 F.2d *1559, 1565* (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.,* 301 F.3d 1343, 1349 (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365 (Fed. Cir. 1999). Moreover, "[I]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.; see also Schering Corp. v. Geneva Pharms.,* 339 F.3d 1373, 1377 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.,* 301 F.3d at 1351; *MEHL/Biophile,* 192 F.3d at 1366). "Thus, when considering a prior art

method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure." *Id.* at 1378. See *Ex parte Satoshi Matsubara,* decided 02/10/2010, from Appeal 2009-006581. The rejections stand.

Relevant Art

18) The art made of record and not currently relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

Olefsky JM (*In*: *Harrison's Principles of Internal Medicine*, 12th Edition, McGraw-Hill Book Company, pages 411-416, 1961) documented in 1961 that the type of diabetes wherein 80 to 90% are 'obese' is type II diabetes. See the first full paragraph on page 414.

Remarks

19) Claims 1-7 and 9-17 stand rejected.

20) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

21) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

22) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

February, 2010